

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF LOUISIANA
MONROE DIVISION

STATE OF LOUISIANA, *et al.*,

Plaintiffs,

v.

XAVIER BECERRA, in his official capacity
as Secretary of the United States Department
of Health and Human Services, *et al.*,

Defendants.

Civil Action No. 3:21-CV-04370-TAD-KDM

**DEFENDANTS' RESPONSE IN OPPOSITION TO PLAINTIFF STATES' CROSS-
MOTION FOR SUMMARY JUDGMENT**

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INTRODUCTION

COVID-19 has killed over a million people and infected over 95 million in the United States alone. *See* Centers for Disease Control and Prevention (“CDC”), COVID Data Tracker (Sept. 12, 2022), <https://perma.cc/47YD-FBQ6>. Those numbers continue to grow as the highly transmissible virus passes easily from person to person. As a result, the pandemic has been devastating for children and families alike. Fortunately, safe and effective vaccines are now approved or authorized for emergency use to protect against COVID-19. And now, the Supreme Court has confirmed that the “unprecedented circumstances” of the COVID-19 pandemic “provide no grounds for limiting the exercise of authorities [the Department of Health and Human Services] has long been recognized to have,” and that such authorities may be used to impose vaccination requirements like the one challenged here. *See Biden v. Missouri*, 142 S. Ct. 647, 654 (2022) (per curiam).

Head Start, a federal grant program, provides funding to aid school readiness for infants, toddlers, and pre-school aged children from low-income families. The COVID-19 pandemic has hit Head Start students and families particularly hard. Many of these students rely on the programs not just for educational purposes, but also for everyday needs, so program closures due to COVID-19 outbreaks have severe negative consequences beyond the classroom. In addition, most Head Start children and personnel come from minority and low-income communities, which have been disproportionately impacted by COVID-19.

The Secretary of Health and Human Services (the “Secretary”) reviewed the evidence and concluded that he had to take urgent measures to protect Head Start students and those interacting with them from infection. As the Sixth Circuit has now confirmed since this Court’s last ruling on Plaintiffs’ motion for a preliminary injunction, “[t]he statute creating the Head Start program gives the Secretary of HHS the power to promulgate regulations to promote the health and wellbeing of the children in the program.” *Livingston Educ. Serv. Agency v. Becerra*, 35 F.4th 489, 491 (6th Cir. 2022), *reh’g denied*, No. 22-1257, 2022 WL 2286410 (6th Cir. June 21, 2022). To carry out this statutory duty, the Secretary issued an Interim Final Rule, Vaccine and Mask Requirements to Mitigate the Spread of COVID-19 in Head Start Programs, 86 Fed. Reg. 68,052-01 (Nov. 30, 2021) (the “Rule”), requiring

that those interacting with Head Start students be vaccinated for COVID-19, or otherwise qualify for an exemption. These individuals were required to receive a single-shot vaccine or to obtain the second shot of a two-dose vaccine by January 31, 2022, or to request an exemption from this requirement from their employer. The Rule also required masking, effective immediately, for all Head Start students over two years old and those Head Start personnel who had contact with students. Just as the Secretary did with the Supreme Court's approval in *Missouri*, 142 S. Ct. at 654, he issued the Rule on an emergency basis and waived a comment period in advance of publication due to an anticipated spike in COVID-19 cases in winter months and a planned return to fully in-person services in January 2022. The Rule was therefore necessary to avoid further disruption to Head Start children's development and learning.

Plaintiffs, a collection of twenty-four states, challenge the Rule on statutory and constitutional grounds. As an initial matter, Plaintiffs—which do not directly receive Head Start funds to operate classrooms under 42 U.S.C. § 9836—lack standing to pursue their claims. Regardless, Plaintiffs' claims lack merit. The Sixth Circuit has already held that the Rule's "vaccine requirement for Head Start program staff, contractors, and volunteers" was likely within HHS's statutory authority. *Livingston*, 35 F.4th at 491. The Secretary reasonably exercised his express statutory authority to arrive at the vaccination and mask Rule. He explained that the need to protect the health and safety of those in the Head Start program compelled him to act now. In exercising this authority Congress lawfully delegated to him under the Spending Clause, he did not run afoul of any provision of the Constitution or the Head Start Act.

After this Court's prior ruling on Plaintiffs' Motion for Preliminary Injunction, the Supreme Court upheld a similar Department of Health and Human Services vaccination requirement in *Missouri*, 142 S. Ct. 647. Considering that decision, a district court in the Eastern District of Michigan recently declined to issue a preliminary injunction of the Rule, holding that Plaintiffs were not likely to succeed on the merits of their claims because the Rule "plainly falls within the Secretary's authority." *Livingston Educ. Serv. Agency v. Becerra*, --- F. Supp. 3d ---, 2022 WL 660793, at *4 (E.D. Mich. Mar. 4, 2022), *appeal filed*, No. 22-1257 (6th Cir. Mar. 30, 2022). Then, in denying an injunction pending appeal in that

matter, the Sixth Circuit held that plaintiffs had “not shown that they will likely prevail on the merits” and that “HHS likely has the statutory authority to issue a vaccine requirement for Head Start program staff, contractors, and volunteers.” *Livingston*, at 491. Thereafter, the Sixth Circuit denied the plaintiffs’ petition for rehearing en banc, with no Sixth Circuit judge having requested a vote. *Livingston Educ. Serv. Agency v. Becerra*, No. 22-1257, 2022 WL 2286410, at *1 (6th Cir. June 21, 2022). Plaintiffs do not even address either of the *Livingston* decisions, which are recent and adverse legal authority directly relevant to this case because they deal with the same Rule that is at issue here. For these reasons, this Court, too, should deny Plaintiffs’ Motion for Summary Judgment.

BACKGROUND

Defendants incorporate the recitation of background facts from their Motion to Dismiss or, in the Alternative, Motion for Summary Judgment. *See* Defs.’ Br. in Supp. of Their Mot. to Dismiss, or in the Alternative, Mot. for Summ. J. (“Defs.’ Br.”), at 3–9, ECF No. 65-1.

On February 28, 2022, the Office of Head Start (“OHS”), within the Administration for Children and Families (“ACF”) of the Department of Health and Human Services (“HHS”), released a statement that it “is reviewing the new CDC recommendations” concerning mask usage and, “[w]hile reviewing the guidelines, OHS will not evaluate compliance with the mask requirement in its program monitoring.” OHS, *CDC Community Levels Recommendations and Mask Wearing*, <https://perma.cc/Y7NW-SQTU>. On August 22, 2022, OHS released another statement reminding programs that they “will not be monitored for mask use given the updated CDC mask guidance.” OHS, *Masks and Vaccines in Head Start Programs*, <https://perma.cc/3M4M-3AF2>. That monitoring policy regarding the mask requirement is still in effect today.

STANDARD OF REVIEW

A moving party is entitled to summary judgment “if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.” Fed. R. Civ. P. 56(a). “Challenges to agency decisions under the APA are properly resolved on motions for summary judgment.” *Berry v. Esper*, 322 F. Supp. 3d 88, 90 (D.D.C. 2018); *see also Pinnacle Armor, Inc. v. United States*, 923 F. Supp. 2d 1226, 1245 (E.D. Cal. 2013) (“Normally, APA cases are resolved on

cross-motions for summary judgment.”); *Smirnov v. Clinton*, 806 F. Supp. 2d 1, 21 n.16 (D.D.C. 2011) (“[M]ost APA cases[] [are resolved] through the consideration of cross motions for summary judgment.”), *aff’d*, 487 F. App’x 582 (D.C. Cir. 2012).

ARGUMENT

I. Plaintiff States Have Not Established Standing.

As an initial matter, Plaintiffs have not established that they have standing to bring this lawsuit. Defendants explained in their Motion to Dismiss, or in the Alternative, Motion for Summary Judgment, that Plaintiffs have not suffered an injury in fact because of the Rule. Defs.’ Br. at 10–14. Defendants now incorporate those same arguments here by reference. Nowhere do Plaintiffs address their standing in their Cross-Motion for Summary Judgment. Plaintiffs bear the burden of establishing that the Court has jurisdiction over their claims, including that Plaintiffs have standing. *See, e.g., Croft v. Governor of Tex.*, 562 F.3d 735, 746 (5th Cir. 2009). They have not met this burden, and the Court has no jurisdiction to hear this case.

II. The Secretary Had Authority to Promulgate the Rule.

Plaintiffs’ challenge to the Secretary’s statutory authority fails under the reasoning of *Missouri*, 142 S. Ct. 647, which upheld a similar interim final rule requiring federally funded healthcare facilities to ensure that their staff were vaccinated against COVID-19. The only court of appeals to consider whether the Secretary had the authority to promulgate the Rule challenged here has determined that he likely did, based in part on the reasoning in *Missouri*. *Livingston*, 35 F.4th at 491. Plaintiffs do not even reference the *Livingston* decision in their briefing. This Court should follow *Livingston* because the Rule is authorized by statute and does not violate any provision of the Head Start Act.

A. The Rule is Authorized by Statute.

The vaccination requirement falls within the Secretary’s “broad rule-making powers.” *Thorpe v. Hous. Auth. of City of Durham*, 393 U.S. 268, 277 n.28 (1969); *see also Nat’l Welfare Rts. Org. v. Mathews*, 533 F.2d 637, 640 (D.C. Cir. 1976) (referencing Congress’s “broad grant of power” to the Secretary). Although this Court previously found a likelihood of success on the claim that HHS lacked statutory authority to implement the Rule, that opinion was issued before the Supreme Court made clear in

Missouri that HHS had the statutory authority to enact a similar COVID-19 vaccine requirement that also derived from the federal government’s authority to protect beneficiaries in a federally funded program. *See Missouri*, 142 S. Ct. at 652. And since the Supreme Court issued the *Missouri* opinion, the Sixth Circuit held that the Rule’s “vaccine requirement for Head Start program staff, contractors, and volunteers” was likely within HHS’s statutory authority. *Livingston*, 35 F.4th at 491. After the Sixth Circuit issued its opinion, it denied the plaintiffs’ petition for rehearing en banc, and no Sixth Circuit judge requested a vote. *Livingston*, 2022 WL 2286410, at *1.

1. The Plain Statutory Text Authorizes the Rule.

An analysis of an agency’s statutory authority “begins with the statutory text”—and, when the text is clear, it “ends there as well.” *Nat’l Ass’n of Mfrs. v. Dep’t of Def.*, 138 S. Ct. 617, 631 (2018) (citation omitted). “The statute creating the Head Start program gives the Secretary of HHS the power to promulgate regulations to promote the health and well-being of the children in the program.” *Livingston*, 35 F.4th at 491. Congress charged the Secretary with adopting, “as necessary,” “standards relating to the condition . . . of [Head Start] facilities,” as well as to address other “administrative . . . standards” necessary for safely carrying out day-to-day operations of Head Start programs. 42 U.S.C. § 9836a(a)(1)(C), (D). Moreover, Congress vested the Secretary with broad authority to issue “such other standards as the Secretary finds to be appropriate” for Head Start agencies and programs. *Id.* § 9836a(a)(1)(E). Binding Supreme Court case law confirms the extent of the Secretary’s authority under these statutes. Addressing similar enabling language in other statutes, the Supreme Court has concluded that this language grants the agency “broad authority.” *Mourning v. Family Publ’ns Serv., Inc.*, 411 U.S. 356, 365 (1973). More specifically, “[w]here the empowering provision of a statute states simply that the agency may ‘make . . . such rules and regulations as may be necessary to carry out the provisions of this Act,’” the Court held that “the validity of a regulation promulgated thereunder will be sustained so long as it is ‘reasonably related to the purposes of the enabling legislation.’” *Id.* at 369 (quoting *Thorpe*, 393 U.S. at 280–81); *see also Livingston*, 2022 WL 660793, at *5. The same is true of statutes that authorize regulations as the Secretary finds to be “appropriate.” *See, e.g., Arkansas v. Oklahoma*, 503 U.S. 91, 105 (1992); *GEO Grp., Inc. v. Newsom*, 15 F.4th 919, 930 (9th Cir. 2021), *vacated*

by 31 F.4th 1109 (9th Cir. 2022) (mem.) (“statutory language—‘appropriate’ and ‘necessary and proper’—is a hallmark of vast discretion” (footnote omitted)).

The vaccination and masking Rule “plainly falls within the Secretary’s authority.” *Livingston*, 2022 WL 660793, at *4. By requiring vaccines and masking for certain Head Start personnel and participants under certain circumstances and subject to exemptions, the Secretary was imposing an “administrative . . . standard” that was “necessary” for the safe management of Head Start programs, 42 U.S.C. § 9836a(a)(1)(C), and a standard “relating to the condition . . . of facilities,” *id.* § 9836a(a)(1)(D). The Rule sought to improve indoor air quality at Head Start facilities by reducing transmission of the virus that causes COVID-19, “which spreads through the air via respiratory droplets.” *Livingston*, 2022 WL 660793, at *4.

At a bare minimum, the Secretary was imposing a “standard[]” he found to be “appropriate” for the Head Start program. 42 U.S.C. § 9836a(a)(1)(E). As noted above, Congress created the Head Start program to provide a healthy and safe learning environment for low-income children across the country. This measure was “appropriate” to protect student health. The agency reasoned that, as of that time, “[g]iven that children under age 5 years are too young to be vaccinated . . . , requiring masking and vaccination among everyone who is eligible are the best defenses against COVID-19.”¹ 86 Fed. Reg. at 68,055. HHS further noted that, in addition to protecting individuals from COVID-19, the requirements will “reduce closures of Head Start programs, which can cause hardship for families, and support the Administration’s priority of sustained in-person early care and education that is safe for children—with all of its known benefits to children and families.” *Id.* at 68,053 (footnote omitted).

Plaintiffs make much of the supposed limits of the term “modify” in 42 U.S.C. § 9836a(a)(1), which directs that “[t]he Secretary shall modify, as necessary, program performance standards by regulation applicable to Head Start agencies and programs under this subchapter.” 42 U.S.C. § 9836a.

¹ After the Rule was issued, the FDA authorized emergency use of both the Moderna COVID-19 vaccine and the Pfizer-BioNTech COVID-19 vaccine for children six months and older in June 2022. *See* “Coronavirus (COVID-19) Update: FDA Authorizes Moderna and Pfizer-BioNTech COVID-19 Vaccines for Children Down to 6 Months of Age,” FDA, <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-moderna-and-pfizer-biontech-covid-19-vaccines-children>.

See Pls.’ Mem. in Supp. of Cross-Mot. for Summ. J. at 9–10, ECF No. 107 (“Pls.’ Mem.”). Plaintiffs argue that the term cannot plausibly be read to allow the Secretary to establish regulations impacting the health of Head Start participants and employees. But even under the Plaintiffs’ own first definition of this term—“[t]o make somewhat different; to make small changes to (something) by way of improvement, suitability, or effectiveness,” *id.* at 10 n.1 (quoting *Modify*, Black’s Law Dictionary (10th ed. 2014))—the Rule is authorized. Required masking of children over age two and required staff vaccinations against a deadly and highly contagious disease were two moderate improvements to a program whose purpose addresses all facets of students’ readiness to succeed in an academic setting, including their health and safety (and that of their families). *See* 42 U.S.C. § 9831(2) (“It is the purpose of this subchapter to promote the school readiness of low-income children by enhancing their cognitive, social, and emotional development . . . through the provision to low-income children and their families of health, educational, nutritional, social, and other services that are determined, based on family needs assessments, to be necessary.”).

“In addition to that broad grant of authority, the statute also specifically provides how the Secretary may remedy ‘health’ risks to children in the program.” *Livingston*, 35 F.4th at 492. The Secretary is charged with issuing deficiencies when programs fail to follow program performance standards, 42 U.S.C. § 9836a(e)(1). A “deficiency” is “a systematic or substantial material failure of an agency in an area of performance that the Secretary determines involves—(i) a threat to the health, safety, or civil rights of children or staff; [or] (iii) a failure to comply with standards related to early childhood development and health services” *Id.* § 9832(2)(A). By the statute’s plain language, then, the Secretary can certainly establish “standards related to early childhood development and health services” and “the health . . . of children or staff” because he can issue deficiencies on failures to follow standards that are a threat to health and safety. *Id.*; *see Missouri*, 142 S. Ct. at 652 (explaining that a vaccination requirement “fits neatly within the language of [a] statute” addressed to the “health and safety of individuals” (internal quotation marks omitted)); *see also Livingston*, 2022 WL 660793, at *5 (discussing the Secretary’s power to identify and correct “deficiencies”). Plaintiffs argue that the Act’s definition of “deficiency” “cannot make up for the lack of a primary grant of authority.” Pls.’

Mem. at 14. But the Sixth Circuit has found that 42 U.S.C. § 9836a(e)(1) provides that grant of authority, and Plaintiffs do not respond to that decision. *See Livingston*, 35 F.4th at 492.

2. The History of Past Head Start Regulations Confirms that HHS Has the Authority to Regulate Health and Safety Within Head Start Programs.

“HHS’s history of regulating the health of Head Start children and staff provides further evidence that the vaccine requirement does not exceed the agency’s statutory authority.” *Id.* In upholding a COVID-19 vaccine requirement for health care workers who treat Medicare and Medicaid patients, the Supreme Court emphasized a similar “longstanding practice of [HHS] in implementing the relevant statutory authorities.” *Missouri*, 142 S. Ct. at 652. The Court rejected the state challengers’ narrow reading of the statute at issue there because it was inconsistent with HHS’s historical practice of imposing “conditions that address the safe and effective provision of healthcare, not simply sound accounting.” *Id.*; *see also Livingston*, 35 F.4th at 492.

“HHS has a history of regulating the health of Head Start staff in order to protect the children in the program.” *Livingston*, 35 F.4th at 492; *see also Missouri*, 142 S. Ct. at 653 (explaining that numerous health and safety regulations fall within the agency’s grant of authority with respect to the Centers for Medicare and Medicaid Services (“CMS”)). These include measures like the vaccine requirement at issue here, and Plaintiff has never objected to any of these similar past measures. These health and wellness standards apply specifically to staff, who are required to have “an initial health examination and a periodic re-examination as recommended by their health care provider in accordance with state, tribal, or local requirements, that include screeners or tests for communicable diseases, as appropriate.” 45 C.F.R. § 1302.93(a). In addition, all Head Start personnel are required to meet the child care standards of the states in which they operate. 42 U.S.C. § 9837(c)(1)(E)(iii); *see also id.* § 9832(2)(A)(vi) (defining a program deficiency in part as the “failure to meet any other Federal or State requirement that the agency has shown an unwillingness or inability to correct”); 45 C.F.R. § 1304.5(a)(2)(viii) (specifying that failure to abide by applicable state requirements is a ground for termination).

Head Start Programs also have a responsibility to “ensure staff do not, because of

communicable diseases, pose a significant risk to the health or safety of others in the program.” *Id.* § 1302.93(a). As explained in Defendants’ Motion to Dismiss, or in the Alternative, Motion for Summary Judgment, numerous other regulations, both in that past and present, have governed the health and safety of staff and program participants alike. *See* 45 C.F.R. § 1302.42(b)(1)(i)-(ii); *id.* § 1302.42(e)(2); *id.* § 1302.47(b)(4)(i)(A) & (b)(7)(iii); *id.* § 1304.3-3(b)(4)–(6) (1975); *id.* § 1304.3-3(b)(8) (1975); *id.* 45 C.F.R. § 1304.3-4(a)(2) (1975); *id.* § 1308 App’x (2015); Head Start Program, 61 Fed. Reg. 57,186-01, 57,210, 57,223 (Nov. 5, 1996); Head Start Performance Standards, 81 Fed. Reg. 61,294, 61,357, 61,433 (Sept. 6, 2016); *see also* Defs.’ Br. at 17–21. As in *Missouri*, this history is a strong indication that the Head Start Act confers broad authority on the Secretary and that the Rule was a permissible exercise of that authority.

Plaintiffs’ argument that “[t]he lack of statutory authority is further supported by the absence of similar regulations in the past,” Pls.’ Mem. at 13, has likewise been rejected by the Supreme Court. *Missouri* recognizes that the federal government may exercise longstanding powers in new ways when faced with new challenges. The Court found it unsurprising that HHS’s “vaccine mandate [went] further than what [HHS] has done in the past to implement infection control” because HHS “has never had to address an infection problem of [the] scale and scope” of the COVID-19 pandemic. *Missouri*, 142 S. Ct. at 653; *accord Bostock v. Clayton Cnty.*, 140 S. Ct. 1731, 1749 (2020) (“[T]he fact that a statute has been applied in situations not expressly anticipated by Congress does not demonstrate ambiguity; instead, it simply demonstrates the breadth of a legislative command” (cleaned up)). That reasoning equally applies here. *See Livingston*, 2022 WL 660793, at *7. It is thus immaterial that HHS had not previously required Head Start personnel to be vaccinated. *See id.*; *see also PennEast Pipeline Co. v. New Jersey*, 141 S. Ct. 2244, 2261 (2021) (“[T]he non-use[] of a power does not disprove its existence.” (citation omitted)). And it is similarly immaterial that a 2014 Congressional Research Service (“CRS”) report allegedly found that the federal government had not implemented vaccine requirements like this one as of that time. *See* Pls.’ Mem. at 11 (citing Jared P. Cole & Kathleen Swendiman, Cong. Rsch. Serv., RS21414, *Mandatory Vaccinations: Precedent and Current Laws* 9 (2014)). If that CRS report were determinative, then the Supreme Court could not have decided *Missouri* as it did. What matters

is that HHS had previously exercised its rulemaking authority to promulgate similar requirements to respond to novel challenges, and the exercise of that authority had never before been challenged.

3. The Major Questions Doctrine and Federalism Canon Do Not Apply Here.

Like the plaintiffs in *Missouri*, Plaintiffs here assert that the Rule violates the major questions doctrine.² Those arguments did not persuade the Supreme Court and they are even less persuasive here. Whereas the interim final rule at issue in *Missouri* affected more than ten million staff at healthcare facilities, *see Missouri*, 142 S. Ct. at 655 (Thomas, J., dissenting), the Rule at issue here affected just 273,000 Head Start workers, 86 Fed. Reg. at 68,077, and a share of the approximately one million volunteers who interact with children in certain in-person settings, *see id.* at 68,068. Plaintiffs' comparison to the OSHA rule at issue in *National Federation of Independent Business v. Department of Labor*, 142 S. Ct. 661 (2022) ("*NFIB*") (per curiam), is misplaced. The Supreme Court deemed the OSHA requirement overbroad in "imposing a vaccine mandate on 84 million Americans." *Id.* at 665. And whereas the Supreme Court found that the OSHA requirement was not statutorily authorized because the threat was "untethered, in any causal sense, from the workplace," *id.* at 666, the threat here existed with full force in a classroom environment with children who were too young to be vaccinated at the time the Rule was issued and where social distancing was often not possible. The Head Start context was more akin to health care facilities, where, the *NFIB* Court recognized, COVID-19 "poses a special danger because of the particular features of an employee's job or workplace" such as "particularly crowded or cramped environments." *Id.* at 665–66. Therefore, "targeted regulations are plainly permissible." *Id.* at 666. In other words, the analogous case is *Missouri*, where the Court held that a vaccination requirement "fits neatly within the language of the statute." *Missouri*, 142 S. Ct. at 652; *see also Livingston*, 2022 WL 660793, at *6 (discussing *NFIB* and *Missouri*).

Moreover, Head Start grants are discretionary, *see* HHS, Grants Policy Statement, at I-1, I-3 to I-4 (Jan. 1, 2007), <https://perma.cc/PME5-9724> ("Grants Policy Statement"), and Head Start

² Compare Pls. Mem. at 7–9, with Response to Application for a Stay, *Biden v. Missouri*, No. 21A240, 2021 WL 8946189, at *22–24 (U.S. Dec. 30, 2021), and Response to Application for a Stay Pending Appeal, *Becerra v. Louisiana*, Nos. 21A240, 21A241, 2021 WL 8939385, at *22–24, *26–28 (U.S. Dec. 30, 2021).

programs cover only a small fraction of children under age 6, *see* 86 Fed. Reg. at 68,077 (estimated number of children enrolled in Head Start programs); Forum on Child & Family Statistics, POP1 Child Population: Number of Children (in Millions) Ages 0-17 in the United States by Age, 1950-2020 and Projected 2021-2050, <https://perma.cc/8EU9-V2HA> (projected number of children under the age of 6). If a particular grantee is unwilling or unable to comply with the Head Start program standards, it is free to relinquish its grant and provide early childhood services through a non-Head Start program instead. The Rule does not “intrude on state police powers” any more than do “the long-standing rules conditioning federal funds on requiring that Head Start personnel do not ‘pose a significant risk’ ‘of communicable disease.’” *Livingston*, 2022 WL 660793, at *10 (quoting 45 C.F.R. § 1302.93(a)).³

The recently decided case of *West Virginia v. EPA*, 142 S. Ct. 2587 (2022), does not alter the inapplicability of the major questions doctrine. HHS did not find “a newfound power” in an “ancillary provision” of a statute, as the Supreme Court found the EPA had done with the Clean Power Plan. *See id.* at 2602, 2613 (concluding that EPA had identified for its regulation a statutory “backwater” that had been “used . . . only a handful of times since the enactment of the statute”). To the contrary, as already discussed, Congress expressly granted the Secretary the authority to issue rules like the Rule at issue here, and HHS has used its authority to issue similar rules regulating health and safety for decades. If anything, *West Virginia* confirms that the major questions doctrine applies only “in certain extraordinary cases” when a regulatory action involves “major policy decisions.” *Id.* at 2609. A regulation that applies only to Head Start Programs and that affected just 273,000 Head Start workers, 86 Fed. Reg. at 68,077, and a share of the approximately one million volunteers, *see id.* at 68,068, nationwide is not such an “extraordinary case.”

³ Plaintiffs also claim that the Rule triggers the major questions doctrine because the agency is regulating in an area of “earnest and profound debate across the country.” Pls.’ Mem. at 8 (quoting *Gonzales v. Oregon*, 546 U.S. 243, 248, 267–68 (2006)). But although the Court in *Gonzales* noted that “[t]he idea that Congress gave the Attorney General such broad and unusual authority through an implicit delegation . . . is not sustainable,” *Gonzales*, 546 U.S. at 267, it never held that a different standard of review applied because of the nature of the regulation. And in any case, the grant of authority here—that the Secretary may issue “such other standards as the Secretary finds to be appropriate” for Head Start agencies and programs, 42 U.S.C. § 9836a(a)(1)(E)—is explicit.

The federalism canon also does not apply here. *See* Pls.’ Mem. at 9. Plaintiffs claim that canon applies because the Rule “seeks to regulate state and local governments, preempt their laws, and invade their traditional police power.” *Id.* It does no such thing, and Plaintiffs do not even explain their allegation that it does. Such a claim is so far afield from the text and purpose of this Rule that the Supreme Court did not even address such an argument in *Missouri*, which dealt with a similar vaccine requirement that was broader than the one at issue here, even though both the *Louisiana* and *Missouri* plaintiffs argued the federalism canon requirement should apply. *See Becerra v. Louisiana*, Resp. to Appl. for Stay Pending Appeal, 21A240, 21A241, 2021 WL 8939385, at *22–24 (U.S. Dec. 30, 2021); *Biden v. Missouri*, Resp. to Appl. for Stay Pending Appeal, 21A240, 2021 WL 8946189, at *20–21 (U.S. Dec. 30, 2021). And following *Missouri*, the *Livingston* district court held that the Rule does not “intrude on state police powers” any more than do “the long-standing rules conditioning federal funds on requiring that Head Start personnel do not ‘pose a significant risk’ ‘of communicable disease.’” *Livingston*, 2022 WL 660793, at *10 (quoting 45 C.F.R. § 1302.93(a)). The Sixth Circuit adopted that reasoning, *see Livingston*, 35 F.4th at 491, and Plaintiffs do not even reference the reasoning of either the district court or the court of appeals.

There is also no reason to think that Congress—which granted the Secretary broad authority to protect Head Start students and personnel precisely because it could not foresee all future threats to participant health and safety—would have regarded a vaccine requirement as a matter requiring clear congressional authorization. *See* 153 Cong. Rec. S14375-02, S14376 (daily ed. Nov. 14, 2007) (statement of Sen. Kennedy) (Head Start “provides the starting point for a child’s day, with a healthy meal each morning and a promise to parents that while they are at work and balancing two jobs, their children will see a doctor and dentist, and receive immunizations.”). To the contrary, “[v]accination requirements are a common feature of the provision of healthcare in America,” *Missouri*, 142 S. Ct. at 653, and have had particular prominence in the education context. *See, e.g., Klaassen v. Trs. of Ind. Univ.*, 7 F.4th 592, 593 (7th Cir. 2021); *see also Jacobson v. Massachusetts*, 197 U.S. 11, 25–35 (1905) (identifying vaccine requirements in the United States and other Western countries in the early 1800s). Thus, “when it comes to vaccination mandates, there was no reason for Congress to be more specific than

authorizing the Secretary to make regulations.” *Florida v. U.S. Dep’t of Health & Hum. Servs.*, 19 F.4th 1271, 1288 (11th Cir. 2021) (in the context of the Secretary’s rulemaking regarding Medicare and Medicaid facilities). At a bare minimum, the Secretary reasonably understood his authority to encompass this responsibility, and that understanding is entitled to deference from this Court. *See Northport Health Servs. of Ark., LLC v. Dep’t of Health & Hum. Servs.*, 14 F.4th 856, 870 (8th Cir. 2021), *pet. for cert. filed*, No. 21-1455 (U.S. May 17, 2022).

In any event, to the extent that either the major questions doctrine or the federalism canon applies, for the aforementioned reasons, Congress spoke clearly by authorizing the Secretary to impose, *inter alia*, “standards relating to the condition . . . of [Head Start] facilities,” as well as to address other “administrative . . . standards” necessary for safely carrying out day-to-day operations of Head Start programs. 42 U.S.C. § 9836a(a)(1)(C), (D). Moreover, Congress gave the Secretary the authority to adopt any “other standards as the Secretary finds to be appropriate.” *Id.* § 9836a(a)(1)(E). “Congress could have limited [the Secretary’s] discretion in any number of ways, but it chose not to do so.” *Little Sisters of the Poor Saints Peter & Paul Home v. Pennsylvania*, 140 S. Ct. 2367, 2380 (2020), *remanded sub nom., Pennsylvania v. Pres., U.S.*, 816 F. App’x 632 (3d Cir. 2020). And courts may not “impos[e] limits on an agency’s discretion that are not supported by the text.” *Id.* at 2381. Indeed, the Supreme Court recently rejected a similar effort to “offer a narrow[] view” of “seemingly broad [statutory] language,” where “the longstanding practice of” HHS “in implementing the relevant statutory authorities [told] a different story.” *Missouri*, 142 S. Ct. at 652.

In short, if it is true that “[t]his case starts and ends with the Major Questions Doctrine,” Pls.’ Mem. at 7, or the federalism canon, then the Court should deny Plaintiffs’ motion.

B. The Rule is Not Contrary to Law.

Plaintiffs allege that the Rule violates five provisions of the Head Start Act. Each of these claims is meritless. *First*, the Rule does not violate “the Head Start Act’s text and structure,” to the extent that is something that can be “violated” in the first place. Pls.’ Mem. at 14–15. Plaintiffs are unclear as to exactly which parts of the Act’s “text and structure” the Rule violates, but they appear to challenge whether the Rule complies with (1) the Head Start Act’s purpose statement; (2) its

requirement that quality of education or care not be reduced; and (3) its requirement that enrollment not be reduced. The latter two are addressed separately both in Plaintiffs' own briefing and below. And as to the Head Start Act's purpose, Plaintiffs do not actually provide any argument as to how the Rule "violates" that purpose. Far from violating the Head Start program's purpose, the Rule is in fact necessary to effectuate that purpose. *See* Defs.' Br. at 14–15.

Second, the Rule does not violate 42 U.S.C. § 9836(a)(2)(B)(x), which requires the Secretary to "take into consideration . . . the unique challenges faced by individual programs, including those programs that are seasonal or short term and those programs that serve rural populations." *See* Pls.' Mem. at 15. Plaintiffs provide no explanation regarding the basis for this claim, but in any event, HHS plainly complied with this provision, as the Rule's preamble confirms. *See, e.g.*, 86 Fed. Reg. at 68,054 ("The Secretary also considered the circumstances and challenges typically facing children and families served by Head Start agencies including the disproportionate effect of COVID-19 on low-income communities served by Head Start agencies and the potential for devastating consequences for children and families of program closures and service interruptions due to SARS-CoV-2 exposures."); *id.* at 68,066 ("ACF also considered whether to tie the universal masking requirement and the testing requirement to SARS-CoV-2 transmission rates" in individual communities but found "[i]t would be burdensome for this program to issue separate guidance across its service area to account for changing transmission levels across those counties").

Third, the Rule does not violate 42 U.S.C. § 9836a(2)(A), which requires that the Secretary "shall consult with experts in the fields of child development, early childhood education, child health care, family services (including linguistically and culturally appropriate services to non-English speaking children and their families), administration, and financial management, and with persons with experience in the operation of Head Start programs." *See* Pls.' Mem. at 15. Plaintiffs state that "[t]he Secretary did not do so before issuing the Mandate," *id.*, but this statement has no basis. The Rule explains that the Secretary consulted with "experts in child health, including pediatricians, a pediatric infectious disease specialist, and the recommendations of the CDC and FDA." 86 Fed. Reg. at 68,054. Absent from 42 U.S.C. § 9836a(a)(2) is any requirement that the Secretary identify by name the specific

experts with whom he consulted. And Plaintiffs do not point to any authority requiring such specificity. *Cf.* 5 U.S.C. § 553(c) (requiring only “a concise general statement of [a final rule’s] basis and purpose”). The personnel who work in the Office of Head Start who created the Rule are of course, themselves, experts in the other listed fields. In any event, even if the Secretary had failed to comply with the statute’s consultation requirement, “consultation during the deferred notice-and-comment period is permissible.” *Missouri*, 142 S. Ct. at 654 (rejecting a similar argument to that which Plaintiffs make here).

Fourth, the Rule does not violate 42 U.S.C. § 9836(a)(2)(C)(ii), which requires the Secretary to “ensure that any such revisions in the standards will not result in the elimination of or any reduction in quality, scope, or types of health, educational, parental involvement, nutritional, social, or other services required to be provided under such standards as in effect on December 12, 2007.” *See* Pls.’ Mem. at 15. Plaintiffs’ entire argument on this point is that, in their opinion, the Rule will “exclud[e] children and reduc[e] eligible staff and volunteers.” Pls.’ Mem. at 15. Plaintiffs’ assertions are speculative; as evidenced by vaccine requirements in other contexts, most people choose to comply with such requirements rather than leave their jobs. *See* 86 Fed. Reg. at 68,056 & nn.52–54. In fact, one of the Secretary’s primary reasons for adopting the Rule was to ensure the continuity of Head Start services, including the “health, educational, parental involvement, nutritional, social, or other services” such facilities provide. 42 U.S.C. § 9836a(a)(2)(C)(ii). The Secretary explained that he

considered the circumstances and challenges typically facing children and families served by Head Start agencies including the disproportionate effect of COVID-19 on low-income communities served by Head Start agencies and the potential for devastating consequences for children and families of program closures and service interruptions due to SARS-CoV-2 exposures.

86 Fed. Reg. at 68,054. The Secretary noted that in the absence of reasonable measures like the Rule, there would likely be intermittent closures of Head Start programs or even a switch to providing services virtually, *id.* at 68,055, which could reduce the quality, scope, or types of services offered to something below pre-2007 levels.⁴

⁴ The vaccine requirement does not eliminate or reduce services from pre-2007 levels when

To the extent parents choose to exclude their own children from Head Start because they do not want them to wear face masks, the efficacy of which is backed by the CDC and the many other sources HHS relied on, that is no different from parents choosing to exclude their children because they do not want them to receive immunizations or to receive all medical treatments on their state's Early and Pediatric Screening, Diagnosis, and Treatment schedule. All of these are already required for participation in Head Start and which none of the twenty-four plaintiff states has ever challenged. *See* 45 C.F.R. § 1302.42(b)(1)(i). The same goes for Head Start personnel, who were already required to undergo several health assessments and screenings and take precautions to avoid transmitting infectious diseases, as already described.

Fifth, the Rule does not violate 42 U.S.C. § 9836a(b)(3)(B), which requires that measures promulgated under the authority of Section 641A “shall not be used to exclude children from Head Start programs.” *See* Pls.’ Mem. at 15–16. As already explained, requiring masking does not reasonably exclude children any more than requiring vaccines and other standard health treatments, which Head Start has done for decades. In fact, HHS promulgated the Rule in large part to make Head Start programs available to more students during the COVID-19 pandemic. *See supra* at 14–15 (explaining how COVID-19 results in program closures, depriving Head Start children across the country from accessing the invaluable resources it provides). HHS plainly followed all the statutory criteria laid out in these statutory provisions. Plaintiffs’ real qualm amounts to a policy disagreement, but that is not a basis for invalidating a rule under the APA.

III. The Rule Does Not Violate the APA’s Notice-and-Comment Requirement.

An agency may issue a rule without advance notice and comment when the agency “for good cause finds . . . that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest.” 5 U.S.C. § 553(b)(B). This exception can be invoked when “delay could result in serious harm.” *Jifry v. FAA*, 370 F.3d 1174, 1179 (D.C. Cir. 2004); *see also Ham. Helicopter Operators*

tuberculosis screening, crib spacing, and temporary exclusion were required for contagious disease control. *See* Defs.’ Br. at 17–21. Rather, it updates the performance standards so they address the realities of the current environment, and therefore, support the continuation of the quality, scope, and types of services at the same or higher level as pre-2007.

Ass'n v. FAA, 51 F.3d 212, 214 (9th Cir. 1995) (good cause waiver properly invoked when there existed a “concern about [a] threat to public safety”). Even though this Court previously found that the Secretary had not properly invoked the good cause exception, Jan. 1, 2022 Mem. Order at 26, since then, the Supreme Court has made clear that good cause can be properly shown in the COVID-19 vaccination context when “something specific” justifies it. *Missouri*, 142 S. Ct. at 654 (citation omitted). And the only court of appeals to consider this issue as applied to this Rule determined that “HHS likely did not violate the Administrative Procedure Act when it promulgated the vaccine requirement through an interim final rule instead of notice-and-comment rulemaking.” *Livingston*, 35 F.4th at 491. Plaintiffs do not reference that Sixth Circuit decision in their briefing.

In *Missouri*, the Supreme Court held that “the Secretary’s finding that accelerated promulgation of the rule in advance of the winter flu season would significantly reduce COVID-19 infections, hospitalizations, and deaths” constituted the “something specific” that is “required to forgo notice and comment.” 142 S. Ct. at 654. (citation omitted). The Secretary found good cause here for similar reasons, *see* 86 Fed. Reg. at 68,058-59, including the prospect of flu season and returning to fully in-person programs in January 2022, *id.* at 68,059. Plaintiffs contend that the onset of winter and flu season are a “crisis of [Defendants’] own making,” Pls.’ Mem. at 17, but both are external occurrences outside Defendants’ control. Just as the Supreme Court held these reasons were sufficient for HHS to invoke the notice and comment exception in *Missouri*, they are sufficient here. *See Livingston*, 35 F.4th at 491 (“Given the similarity between the interim final rule at issue here and the rule that the Supreme Court upheld in *Missouri*, the plaintiffs are unlikely to prevail on their claim that the lack of notice-and-comment rulemaking violated the Administrative Procedure Act.”).

The Secretary also gave additional reasons showing an “immediate need” to adopt the Rule. Recognizing the “potential for the rapid and unexpected development and spread of additional new and more transmissible variants,” 86 Fed. Reg. at 68,053, the Secretary found that any delay in issuing the Rule would “endanger the health and safety of staff, children and families, and be contrary to the public interest,” *id.* at 68,059. The emergence of the highly transmissible Delta variant, which had already “resulted in greater rates of cases and hospitalizations among children,” heightened the

urgency of the Rule as well. *Id.* at 68,053. In short, “[t]he interim final rule contains ample discussion of the evidence in support of a vaccine requirement and the Secretary’s justifications for enacting the requirement.” *Livingston*, 35 F.4th at 491.

Plaintiffs further argue that the Secretary’s “delay” in promulgating the Rule undercuts his ability to invoke the good cause exception. Pls.’ Mem. at 17. But as Plaintiffs acknowledge, *Missouri* considered and rejected the same argument, and the fact that the Secretary took a few more weeks to develop the Rule at issue here does not change that. *See Missouri*, 142 S. Ct. at 654. The district court in *Livingston*—an opinion interpreting *Missouri*—found as much. *Livingston*, 2022 WL 660793, at *8 (“[T]he 82 days that it took to publish the Rule after it was first announced on September 9, 2021, did not ‘constitute[] delay inconsistent with the Secretary’s finding of good cause.’”) (quoting *Missouri*, 142 S. Ct. at 654).

IV. The Rule Is Not Arbitrary and Capricious.

Plaintiffs’ claims that the Rule is arbitrary-and-capricious fare no better. *See Livingston*, 35 F.4th at 491 (adopting the reasoning of the district court that the Rule is not arbitrary and capricious). Agency action must be upheld in the face of an arbitrary-and-capricious challenge so long as the agency “articulate[s] a satisfactory explanation for [the] action including a rational connection between the facts found and the choice made.” *Little Sisters of the Poor*, 140 S. Ct. at 2383 (citation omitted). A court’s review is “narrow” and the court “is not to substitute its judgment for that of the agency.” *Motor Vehicle Mfrs. Ass’n of the U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983); *see also Ky. Coal Ass’n v. Tenn. Valley Auth.*, 804 F.3d 799, 801 (6th Cir. 2015) (APA standard is not an “invitation for judicial second-guessing”). Under this “deferential” standard, a court “simply ensures that the agency has acted within a zone of reasonableness and, in particular, has reasonably considered the relevant issues and reasonably explained the decision.” *FCC v. Prometheus Radio Project*, 141 S. Ct. 1150, 1158 (2021). Critically, “mere policy disagreement is not a basis for a reviewing court to declare agency action unlawful.” *N.C. Fisheries Ass’n v. Gutierrez*, 518 F. Supp. 2d 62, 95 (D.D.C. 2007).

Furthermore, the Court’s review of Plaintiffs’ APA claims should be confined to the record before the Secretary. “[T]he focal point for judicial review should be the administrative record already

in existence [on the basis of which the agency's determination was made], not some new record made initially in the reviewing court.” *La. Env't Soc'y, Inc. v. Dole*, 707 F.2d 116, 119 (5th Cir. 1983) (quoting *Camp v. Pitts*, 411 U.S. 138, 142 (1973)). What matters, therefore, is the evidence that was available and considered by the Secretary at the time the Rule was issued. *See id.*; *see also Lee Mem'l Hosp. v. Burwell*, 109 F. Supp. 3d 40, 46–47 (D.D.C. 2015) (remarking that the administrative record “consists of all documents and materials directly or indirectly considered by agency decision-makers”). “[W]hen a party seeks review of agency action under the APA . . . , the district judge sits as an appellate tribunal.” *Rempfer v. Sharfstein*, 583 F.3d 860, 865 (D.C. Cir. 2009) (quoting *Am. Bioscience, Inc. v. Thompson*, 269 F.3d 1077, 1083 (D.C. Cir. 2001)). Thus, the Court's review “is based on the agency record and limited to determining whether the agency acted arbitrarily or capriciously.” *Id.* Plaintiffs rely on numerous articles and documents going to the merits, for example, records addressing the wisdom of vaccine and masking requirements, including several that were created *after* the Rule was issued. *See* Pls.' Mem. at 18–22. Those sources are not proper subjects of APA review because they were not before the Secretary and are irrelevant to his decision, and in any event would not help Plaintiffs' claims because the Secretary's decision is supported by the record considered by the agency.

Here, the Secretary adopted a reasonable Rule after considering the relevant issues. The fifty-page Rule reasonably explains the Secretary's decision, setting forth the justifications, weighing costs and benefits, considering alternative approaches, and providing an economic impact analysis. *See generally* 86 Fed. Reg. at 68,052. Plaintiffs claim that the Rule is arbitrary and capricious in eight ways. Pls.' Mem. at 17. None of Plaintiffs' claims has merit. Although this Court previously stated that some of these claims raised “interesting issues,” *See* PI Order at 28, the Supreme Court has since rejected similar arbitrary-and-capricious claims against the CMS vaccine requirement, *see Missouri*, 142 S. Ct. at 653–54, and another court has found that the Rule is not arbitrary and capricious, *see Livingston*, 2022 WL 660793, at *8; *see also Livingston*, 35 F.4th at 491 (“adopt[ing] the reasoning of the district court” as to the reasons why “plaintiffs have not shown that they will likely prevail on the merits,” including as to their arbitrary-and-capricious claim). Plaintiffs have not responded to *Livingston's* reasoning.

First, Plaintiffs argue that the Rule overlooked that staff or students might leave the program due to the Rule, or overlooked the effects on specific groups, like children with special needs or underserved communities. *See* Pls.’ Mem. at 18–19. But the Secretary considered these factors. The Secretary explicitly considered that the Rule might result in staff vacancies and stated that “[t]o value the countervailing risk of staff vacancies, [the Secretary] adopt[s] an assumption that each Head Start staff that quits in response to the interim final rule will leave a vacancy that lasts an average of two weeks.” 86 Fed. Reg. at 68,091. The Secretary also explained that, “[f]or each COVID-19 case averted, parents and caretakers experienced 190 hours of time savings.” *Id.* One of the primary goals of the Rule is to reduce instances in which a positive case of COVID-19 in the classroom results in program closures and service interruptions. *See id.* at 68,054. Thus, the Secretary considered that some personnel and students may voluntarily leave the Head Start program over the new requirements, but nevertheless determined that those costs would be outweighed by the benefits of reducing COVID-19 transmission based on the evidence available at the time. *See La. Env’t Soc’y, Inc.*, 707 F.2d at 119. Additionally, the Rule provides exemptions from the vaccine requirement for personnel “who cannot be vaccinated because of a disability under the ADA, medical condition, or sincerely held religious beliefs, practice, or observance.” 86 Fed. Reg. at 68,061 (footnote omitted).

While Plaintiffs argue that the Secretary failed to consider children with special needs, the Secretary did consider them, providing exceptions to the masking requirements for “persons who cannot wear a mask, or cannot safely wear a mask, because of a disability as defined by the Americans with Disabilities Act (ADA), consistent with CDC guidance on disability exemptions; and for children with special health care needs, for whom programs should work together with parents and follow the advice of the child’s health care provider for the best type of face covering.” *Id.* at 68,060. Relying on CDC guidance from November 10, 2021 recommending “universal indoor masking for ECE [early childhood education and child care] programs for everyone aged 2 years and older,” the Secretary determined that “ECE program staff can model consistent and correct use for children aged 2 years or older in their care.” *Id.* at 68,054. CDC is an agency with scientific expertise in protection from infectious diseases, and thus, it was reasonable for the Secretary to rely on the most recent

recommendation of CDC at the time, over competing information from non-governmental agencies. *See La. Env't Soc'y, Inc.*, 707 F.2d at 119; *Balt. Gas & Elec. Co. v. Nat. Res. Def. Council, Inc.*, 462 U.S. 87, 103 (1983) (recognizing that courts must be at their “most deferential” when reviewing an agency’s “scientific determination”); *N.C. Fisheries Ass’n*, 518 F. Supp. 2d at 95 (“[M]ere policy disagreement is not a basis for a reviewing court to declare agency action unlawful.”). Courts are not to “second-guess[]” an agency’s “weighing of risks and benefits” associated with a rulemaking. *Dep’t of Com. v. New York*, 139 S. Ct. 2551, 2571 (2019).

The Rule also explicitly considers its impact on underserved children and communities in particular, concluding that the Rule would “promote[] public and community health and health equity for children and staff in Head Start programs” “[g]iven the disproportionate burden of COVID-19 deaths and lower vaccination rates among racial and ethnic minority groups.” 86 Fed. Reg. at 68,055–56 (footnotes omitted); *see also id.* at 68,058 (“Program closures [from positive COVID-19 cases] impede Head Start families from participating in the workplace, impose financial hardship on low wage workers who may not have paid time off to care for children who are in quarantine, create instability for children and families who depend on the Head Start program, and delay a full economic recovery for the nation.”).

Second, contrary to Plaintiffs’ argument, *see* Pls.’ Mem. at 19–20, HHS did consider alternatives to the Rule. Indeed, the Rule has an entire section outlining several options considered but rejected by the Secretary. 86 Fed. Reg. at 68,066. Plaintiffs claim that the Rule is arbitrary because it did not recognize natural immunity as an alternative to vaccination or mask wearing, and because it insufficiently considered changes in vaccine efficacy over time. *See* Pls.’ Mem. at 19–20. The Secretary considered scientific literature on the efficacy of vaccines at the time it issued the Rule and concluded that “[t]he COVID-19 vaccines are the safest and most effective way to protect individuals and the people with whom they live and work from infection and from severe illness and hospitalization if they contract the virus.” 86 Fed. Reg. at 68,054–55; *see La. Env’t Soc’y, Inc.*, 707 F.2d at 119. The Rule

supports this finding with numerous scientific studies.⁵ 86 Fed. Reg. at 68,055 & nn.31–36. “When examining this kind of scientific determination, as opposed to simple findings of fact, a reviewing court must generally be at its most deferential.” *Balt. Gas & Elec. Co.*, 462 U.S. at 103. The Secretary reasonably concluded that, based on the most recent evidence at that time, vaccinations were a superior mitigation strategy, regardless of a recipient’s supposed “natural immunity.”

The Secretary’s decision was based on the most reliable scientific evidence available at the time, especially given the contrast between the inexorable and, at times, surging pace of the pandemic and the necessarily measured pace of scientific research. It is common for an agency “not [to] have perfect empirical or statistical data,” particularly on complex issues like the interplay between protection provided by prior infection and vaccines, or the efficacy of vaccination over time; the APA does not require such evidence before an agency may act. *Prometheus Radio Project*, 141 S. Ct. at 1160; *see also San Luis & Delta-Mendota Water Auth. v. Locke*, 776 F.3d 971, 995 (9th Cir. 2014) (“[Even] if the only available data is ‘weak, and thus not dispositive,’ an agency’s reliance on such data ‘does not render the agency’s determination arbitrary and capricious.’” (quoting *Greenpeace Action v. Franklin*, 14 F.3d 1324, 1336 (9th Cir. 1992))). Indeed, many, if not most, statistical analyses have some limitations regarding sample size, etc., but that does not mean that they do not also provide valuable information upon which an agency may rely. Here, the agency “made a reasonable predictive judgment based on the evidence it had,” *Prometheus Radio Project*, 141 S. Ct. at 1160, which is all the APA requires.

Third, the Secretary’s rationale for the Rule—to mitigate the spread of COVID-19 in Head Start programs—was not pretextual. *Contra* Pls.’ Mem. at 20. Plaintiffs try to cast the Rule as a sinister

⁵ Indeed, the Secretary considered scientific literature that acknowledged and considered the possibility that vaccine efficacy decreases as time from vaccination increases, but still concluded that COVID-19 vaccines were highly protective. *See* Fowlkes, A., Gaglani, M., Groover, K., et al. Effectiveness of COVID–19 Vaccines in Preventing SARS–CoV–2 Infection among Frontline Workers Before and During B.1.617.2 (Delta) Variant Predominance—Eight U.S. Locations, December 2020–August 2021, Morbidity and Mortality Weekly Report, Aug. 27, 2021, <https://perma.cc/5YKH-QYR4> (finding that the evidence “further affirm[ed] the highly protective benefit of full vaccination up to and through the most recent summer U.S. COVID-19 pandemic waves” despite some apparent decrease in vaccine effectiveness, and noting that “[vaccine effectiveness] might also be declining as time since vaccination increases”) (cited at 86 Fed. Reg. 68,055 n.33).

attempt “aimed at increasing vaccination rates throughout American society, writ large.” *Id.* But there was no need for the Secretary to “pigeonhole the Mandate into the Head Start Act’s statutory factors,” *id.*—the Act’s statutory factors have long permitted the Secretary to include health-related standards, *see supra* Section II.A.1–2. It was also not surprising that, given the copious evidence available at the time the Rule was promulgated about the effectiveness of vaccines in reducing the spread of COVID-19, *e.g.*, 86 Fed. Reg. at 68,059, other federal agencies, like OSHA or CMS, would have concluded that carrying out their own missions required vaccination of individuals who participate in their programs or that are regulated by them. The thorough explication of the Secretary’s justifications and reasons in the fifty-page Rule likewise rebuts any accusation that his reasons were pretextual. And, of course, to the extent that the Rule was part of a broader focus by the administration to protect the health and safety of Americans, there is nothing unusual or unlawful about this. “[A] court may not set aside an agency’s policymaking decision solely because it might have been influenced by political considerations or prompted by an Administration’s priorities.” *Dep’t of Com.*, 139 S. Ct. at 2573. Unlike in *Department of Commerce v. New York*, here there is not a “significant mismatch between the decision the Secretary made and the rationale he provided.” *Id.* at 2575.

Fourth, Plaintiffs’ allusion to “reliance interests,” Pls.’ Mem. at 20, is unavailing. Plaintiffs refer to their interest “in public and private Head Start programs continuing to operate under existing rules,” *id.*, but the Rule analyzed its costs and benefits and concluded that the benefits outweighed the costs. Likewise, Plaintiffs refer to Head Start providers’ interests “in staffing their facilities under the existing rules without facing this new Mandate that threatens their workforce,” *id.*, which appears to reduce to their same argument that the Rule will cause employees to leave or endanger Head Start services, and to Head Start workers’ interests “in selecting a job and building a career under the existing rules,” *id.* at 21. That, in turn, appears to reduce to Plaintiffs’ same argument that the Rule will harm Head Start employees. None of these interests implicates reliance in the traditional sense, *i.e.*, Plaintiffs do not allege that they undertook actions to their detriment because of representations that the agency had made to them about the future. Indeed, it would be difficult for Plaintiffs to argue that they relied on the prior rules to their detriment, given that they do not directly receive Head Start grants to operate

classrooms, and that they elsewhere question why the Secretary “did not require children to wear masks in the Head Start program before now, including when case numbers were higher.” Pls.’ Mem. at 21–22. Furthermore, Plaintiffs understood that the performance standards were subject to modification, as the Head Start Act explicitly instructs the Secretary to “modify” them “as necessary.” 42 U.S.C. § 9836a(a)(1). In any event, as has previously been discussed, the Secretary considered that the Rule might result in some Head Start employees choosing to leave their jobs but determined that the benefits of the Rule outweighed that risk. That Plaintiffs would have reached a different conclusion had they been weighing the potential benefits does not mean that the Rule is arbitrary or capricious.

Fifth, Plaintiffs misapprehend the issue when they argue that the Secretary failed to consider conflicting state laws. Pls.’ Mem. at 21. The Secretary recognized that some states have differing requirements (and indeed, if all states had uniform requirements that matched the Rule, the Rule would be unnecessary). As the Rule noted, pursuant to the Supremacy Clause, the Rule preempts any conflicting state laws as to Head Start programs, relieving any issues of uncertainty regarding which requirements Head Start providers should implement. *See, e.g.*, 86 Fed. Reg. at 68,061 (“[T]his IFC preempts the applicability of any state or local law providing for exemptions to the extent such law provides broader exemptions than provided for by federal law and are inconsistent with this IFC.”); *id.* at 68,063 (“In these cases, consistent with the Supremacy Clause of the Constitution, the agency intends that this rule preempts State and local laws to the extent the State and local laws conflict with this rule.”). The Secretary did not take this step lightly, and as part of its preemption analysis, HHS noted that it had “considered other alternatives [to preempting state law] (for example, relying entirely on measures such as voluntary vaccination, source control alone, and physical distancing) and . . . concluded that the mandate established by this rule is the minimum regulatory action necessary to achieve the objectives of the statute.” *Id.*

Sixth, the Rule is not arbitrary and capricious for failure to “account for differences in” community measures, transmission levels, hospitalization levels, or levels of infection across communities.” Pls.’ Mem. at 21 (quoting *BST Holdings, LLC v. OSHA*, 17 F.4th 604, 612 (5th Cir.

2021)).⁶ The Secretary considered these issues, including whether to tie requirements to community transmission rates. 86 Fed. Reg. at 68,066. However, given the number of Head Start grant recipients and the fact that many serve entire states or cross state lines, the Secretary concluded that such an approach “would be burdensome for” grant recipients operating over a large area. *Id.* It is not arbitrary or capricious for the Secretary to recognize that “children benefit from routine and predicability” and to “prioritiz[e] a clear and transparent policy that is easy for grantees to follow across their service areas.” *Id.* And an agency’s action should be upheld where it acts within the “zone of reasonableness.” *Prometheus Radio Project*, 141 S. Ct. at 1158; *see also Nat’l Shooting Sports Found., Inc. v. Jones*, 716 F.3d 200, 214 (D.C. Cir. 2013) (“An agency has wide discretion in making line-drawing decisions and the relevant question is whether the agency’s [determination is] within a zone of reasonableness, not whether [it is] precisely right.” (cleaned up)).

Seventh, Plaintiffs speculate that some harm may occur because Head Start students attend school with non-Head Start students—without citing anything to substantiate this theoretical harm—and that the agency overlooked this potential harm. Pls.’ Mem. at 21. The Secretary, of course, only has authority to implement standards for Head Start programs, not other programs, and it is not arbitrary or capricious for it to cabin itself to that limitation. To the extent that there are discrepancies among policies applying to students at the same school, they result from state and local school districts’ decisions not to implement mask requirements that align with the federal standards for Head Start.

Finally, the Rule *did* engage with the “fundamental questions” that Plaintiffs argue it omitted. Pls.’ Mem. at 21. As to why the Secretary did not implement a mask requirement “before now, including when case numbers were higher and everybody was unvaccinated,” *id.* at 21–22, the Rule notes, among other considerations, that “the advent of the Delta variant and the potential for new variants,” and the “return to fully in-person services” in January 2022, justified a more robust

⁶ Plaintiffs liken the supposed overbreadth of this rule to the OSHA rule that the Fifth Circuit found to be “staggeringly overbroad.” Pls.’ Mem. at 21 (quoting *BST Holdings*, 17 F.4th at 615). There is no comparison. That Rule applied to “2 out of 3 private-sector employees in America.” *BST Holdings*, 17 F.4th at 615. This Rule affects just 273,000 Head Start workers, 86 Fed. Reg. at 68,077, and a share of the approximately one million volunteers who interact with children in certain in-person settings, *see id.* at 68,068.

approach, particularly given that “uptake of vaccination among Head Start staff has not been as robust as hoped for and has been insufficient to create a safe environment for children and families.” 86 Fed. Reg. at 68,054. In addition, on November 10, 2021, the CDC “issued updated guidance to early childhood education and child care (ECE) programs,” which, among other things, recommended “universal indoor masking for ECE programs for everyone aged 2 years and older.” *Id.* The changed circumstances, including the emergence of the Delta variant and the updated CDC recommendations shortly before the Secretary issued the Rule, justified the change in course. This is not unusual. “[A]gencies are expected to reevaluate the wisdom of their policies in response to changing factual circumstances.” *COMPTTEL v. FCC*, 978 F.3d 1325, 1335 (D.C. Cir. 2020). There is no heightened standard when an agency changes its policy so long as the agency shows that “the new policy is permissible under the statute, that there are good reasons for it, and that the agency *believes* it to be better, which the conscious change of course adequately indicates.” *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009). And while Plaintiffs criticize the Rule for including a masking requirement where President Biden’s COVID-19 action plan did not, Pls.’ Mem. at 22, the Secretary considered an alternative that did not include a masking requirement but concluded, in weighing the available evidence, that adding the masking requirement “will result in additional, unquantified reductions in mortality and morbidity risks to Head Start children and families, and to the general public.” 86 Fed. Reg. at 68,100. That Plaintiffs would have reached a different conclusion does not mean that the Secretary acted arbitrarily or capriciously.

V. The Rule Complies with the Treasury and General Government Appropriations Act of 1999.

Plaintiffs’ contention that the agency violated the Treasury and General Government Appropriations Act by not conducting a family impact assessment, Pls.’ Mem. at 22–23, is a red herring. As explained in Defendants’ prior briefing, that statute is not judicially enforceable. *See* Defs.’ Br. at 36–38. In any event, the agency explained that it had followed the requirements of that statute, stating, “ACF believes it is not necessary to prepare a family policymaking assessment . . . because the

action it takes in this interim final rule will not have any impact on the autonomy or integrity of the family as an institution.” 86 Fed. Reg. at 68,062.

Plaintiffs include a single conclusory sentence that the Rule “intrudes into fundamental decisions about whether a child must wear a mask at school, imposes obligations on parents picking children up from school, and goes straight to the heart of the allocation of power between government and family.” Pls.’ Mem. at 22–23. But they do not provide any support for this statement. Because Plaintiffs fail to argue that ACF was wrong to determine that the Rule would not impact family well-being, Plaintiffs cannot argue that the assessment was required.

The Rule simply requires two commonsense measures that slow the spread of a highly contagious virus while children are with their peers and personnel at Head Start facilities. When children are with their families at home or anywhere else, they are not covered by the Rule, so they are free to wear masks or not, as they and their families so choose. And as Defendants have noted, *see* Defs.’ Br. at 37–38, the seven factors included in the family impact assessment do not apply to the requirements of the Rule. Because these factors do not apply to the Rule, and Plaintiffs do not even attempt to argue how they would, Plaintiffs’ claim should be dismissed.

VI. The Rule Does Not Violate the Nondelegation Doctrine, the Spending Clause, the Tenth Amendment, or the Anti-Commandeering Doctrine.

First, Plaintiffs’ nondelegation challenge fails. Plaintiffs contend that the Head Start Act lacks an intelligible principle because, along with authorizing the Secretary to issue “standards relating to the condition . . . of [Head Start] facilities,” as well as to address other “administrative . . . standards” necessary for safely carrying out day-to-day operations of Head Start programs, 42 U.S.C. § 9836a(a)(1)(C), (D), it permits him to adopt “such other standards as the Secretary finds to be appropriate” for Head Start agencies and programs, *id.* § 9836a(a)(1)(E). Pls.’ Mem. at 23. But many Congressional statutes use similar terminology, and Plaintiffs have “not identified a single case which finds one of those statutes to be in violation of” the nondelegation doctrine. *Livingston*, 2022 WL 660793, at *9. Any standard promulgated by the Secretary must be consistent with the Head Start Act’s purpose of protecting Head Start participants and personnel. *See, e.g., Arkansas*, 503 U.S. at 105.

The Secretary's authority in § 9836a(a)(1)(E) meets the "minimal standard" required for the nondelegation doctrine. *Livingston*, 2022 WL 660793, at *9.

Second, the Rule does not violate the Tenth Amendment. The Head Start Act was passed pursuant to Congress' Spending Clause authority, and when "a power is delegated to Congress in the Constitution, the Tenth Amendment expressly disclaims any reservation of that power to the States." *New York v. United States*, 505 U.S. 144, 156 (1992). The Secretary issued the Rule pursuant to the authority that Congress delegated to him in the Head Start Act. *See supra* Section II. And even if the Rule displaces state law as to the entities that accept Head Start funds, Pls.' Mem. at 24, that does not violate the Tenth Amendment. *See Hodel v. Va. Surface Mining & Reclamation Ass'n*, 452 U.S. 264, 291 (1981) (The federal government does not "invade[] areas reserved to the States by the Tenth Amendment simply because it exercises its authority" under the Constitution, even "in a manner that *displaces* the States' exercise of their police powers.") (emphasis added). Congress's Spending Clause authority applies even when Congress legislates "in an area historically of state concern." *Sabri v. United States*, 541 U.S. 600, 608 n.* (2004). Because the Rule rests on authority specifically delegated to the federal government, it does not violate the Tenth Amendment. *See Brackeen v. Haaland*, 994 F.3d 249, 310 (5th Cir. 2021) ("[T]he Federal Government, when acting within a delegated power, may override countervailing state interests, whether those interests are labeled traditional, fundamental, or otherwise." (citation omitted)), *cert. granted*, 142 S. Ct. 1205 (2022).

Third, the Rule does not violate the anti-commandeering doctrine because it does not "use the States as implements of [federal] regulation." *New York*, 505 U.S. at 161. Head Start is a federal discretionary grant program that administers funding, not one that uses state officials to enforce federal policy. *See* Grants Policy Statement; *contra New York*, 505 U.S. at 175 (federal statute required state legislative and executive officials to enact a state regulation defined by the federal statute); *Printz v. United States*, 521 U.S. 898, 935 (1997) (federal statute that required local law enforcement officials to perform background checks); *Murphy v. Nat'l Collegiate Athletic Ass'n*, 138 S. Ct. 1461, 1478–79 (2018) (federal statute prevented state legislatures from enacting certain laws). The Rule has not "conscript[ed]" anyone because it only applies to entities that voluntarily and freely agree to participate

in the Head Start grant program. *See* Pls.’ Mem. at 24 (citation omitted). It is a spending program that does not require anything of state officials, let alone coerce action. *See New York v. U.S. Dep’t of Just.*, 951 F.3d 84, 115 (2d Cir. 2020), *cert. dismissed*, 141 S. Ct. 1291 (2021).

Fourth, the Rule does not run afoul of the Spending Clause simply because it requires those states that accept Head Start funding (none of which are Plaintiffs here) to comply with additional performance standards. Pls.’ Mot. at 24–25. Section 9836a(a)(1) delegates to the Secretary the authority to promulgate performance standards. These performance standards are conditions of participation in the Head Start program. *See NFIB v. Sebelius*, 567 U.S. 519, 579 (2012) (Congress “may attach appropriate conditions to federal taxing and spending programs to preserve its control over the use of federal funds.”). And the conditions set forth in the Rule are unambiguous: (1) universal masking for those two years or older; (2) vaccination for all Head Start personnel; and (3) weekly testing for those exempted from vaccination. *See Pennhurst State Sch. & Hosp. v. Halderman*, 451 U.S. 1, 25 (1981). “Grant recipients are aware when they apply to the program that they must abide by the Head Start Performance Standards and that they are free to leave the program and operate outside the Secretary’s standards if they choose to do so.” *Livingston*, 2022 WL 660793, at *9. The Rule also “puts grant recipients on notice that they are obligated to comply with the vaccine requirement to continue receiving Head Start funding.” *Id.* Plaintiffs have therefore not established a Spending Clause violation.

VII. Any Relief Granted to Plaintiffs Should Be Limited in Scope.

Finally, if the Court finds that Plaintiffs are entitled to summary judgment (and it should not), any relief should be limited in scope. Plaintiffs have not attempted to demonstrate that they meet the requirements for a permanent injunction. *See eBay Inc. v. MercExchange, LLC*, 547 U.S. 388, 391 (2006) (to merit a permanent injunction, “a plaintiff must demonstrate: (1) that it has suffered an irreparable injury; (2) that remedies available at law, such as monetary damages, are inadequate to compensate for that injury; (3) that, considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction”).

If the Court decides to set aside any part of the Rule under the APA, that relief should be no broader than necessary to remedy any demonstrated irreparable harms of the specific Plaintiffs in this case. “A plaintiff’s remedy must be tailored to redress the plaintiff’s particular injury.” *Gill v. Whitford*, 138 S. Ct. 1916, 1934 (2018). Plaintiffs’ decision to bring APA claims does not necessitate a nationwide remedy. *See, e.g., Louisiana v. Becerra*, 20 F.4th 260, 263–65 (5th Cir. 2021) (vacating nationwide scope of injunction in APA challenge). Accordingly, the Court should construe the “set aside” language in Section 706(2) as applying only to the named Plaintiffs.

Nationwide relief would be particularly harmful here. Another challenge to the Rule is currently pending before the Sixth Circuit. *See Livingston Educ. Serv. Agency v. Becerra*, No. 22-1257 (6th Cir. 2022). Other district courts have also already considered similar challenges to the Rule, with differing outcomes. *See Livingston*, 2022 WL 660793, at *11 (denying motion for preliminary injunction); *Texas v. Becerra*, No. 5:21-cv-300, 2021 WL 6198109 (N.D. Tex. Dec. 31, 2021) (granting motion for preliminary injunction limited to Texas); *Etherton v. Biden*, No. 1:22-cv-195 (E.D. Va.). Nationwide relief would render the decisions by these district courts meaningless as a practical matter.

Additionally, the Court should only set aside those aspects of the Rule, if any, for which the Court finds that Plaintiffs are entitled to relief. The Supreme Court has held a regulation severable where severance would “not impair the function of the statute as a whole, and there is no indication that the regulation would not have been passed but for its inclusion.” *K Mart Corp. v. Cartier, Inc.*, 486 U.S. 281, 294 (1988) (invalidating only the provision of a regulation that exceeded the agency’s statutory authority). Severability clauses, such as the one in the Rule, *see* 86 Fed. Reg. at 68,060, create a presumption that the validity of the entire regulation is not dependent on the validity of any specific unlawful provision if that unlawful provision would not impair the function of the regulation as a whole. *Alaska Airlines, Inc. v. Brock*, 480 U.S. 678, 686 (1987).

CONCLUSION

For the foregoing reasons, this Court should deny Plaintiffs’ Cross-Motion for Summary Judgment.

Dated: September 14, 2022

Respectfully submitted,

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